



CLINICAL REFERENCE  
LABORATORY

FR Doc # 04-7984  
PUBLIC COMMENT 8408066

July 7, 2004

Walter F. Vogl, Ph.D.  
Via Fax 301-443-3031

Re: FR. Doc 04-7984

The alternate specimen portion of this document is a sham; perpetuated, I assume, in response to political pressure generated by lobbyists for industries that have invested heavily in developing these as yet unproven, limited, unreliable, litigious, and racially biased, etc., testing methods. The Department should withdraw this document as a proposed rule and concentrate instead on further improving the present, scientifically mature urine based program. Progress toward this end is noted in the changes in urine cutoff concentrations, but the changes should be more comprehensive. At present, for every positive drug test reported, the Department knowingly allows a drug user to be reported as negative: heroin users with 6-AM positive but less than 10 ng/ml; meth users with amphetamine positive but less than 200 ng/ml; marijuana users with THCA greater than 10 but less than 15; etc. Adding alternate matrices to the mix would, in addition to the other problems, exacerbate this condition.

And speaking of cutoffs, where is the documentation showing the interrelationship in concentrations between the various matrices? Will Federal employees' drug use be evaluated by different criteria depending on the matrix utilized for testing?

My lab is participating in the alternate matrices PT program. The results are scary with respect to labs' range of results and their inability to measure cutoff concentrations for all drugs with established technology.

Oral fluid isn't good enough for marijuana, so a double collection (O.F. and urine) should be used? HA! Who thought of that? POCTs that meet lab based testing requirements for cutoffs, consistency and QA/QC? Right. These two examples may be evidence that whoever proposed this stuff was not themselves subject to a drug testing program.

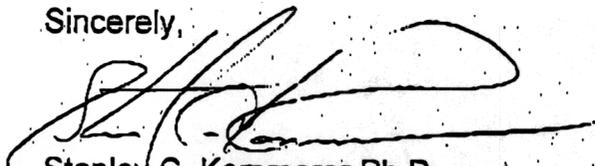
Finally, another subject—funding. Who will be funding the added monitoring of collection sites, labs and MRO's required for the alternative matrices programs. If the plan is to hit the already strapped labs for, in some cases, more than the annual six figures cost required for their participation in the program, it may be akin to killing the goose who is laying the golden eggs.



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Between Sec. 1.1 and Sec. 16.4, I have listed more than fifty examples of ambiguity, unrealistic expectations and/or procedural omissions that I am not including in this comment letter. Suffice it to say that should this proposal become regulation, enrollment in the nation's law schools will surely soar. Please withdraw the alternate matrices part of this revision and concentrate on improving what we already have. Though the Department has really messed up SVT testing with respect to dilute and substituted specimens, at least that is not a program breaker. This alternate matrix rule, as written, could be.

Sincerely,



Stanley C. Kammerer Ph.D.  
VP and Director of Toxicology